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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,005	07/18/2001	Henry Yue	PF-0599-2 DIV	9313

7590 02.14.2002

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PATENT DEPARTMENT
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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	J

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/909,005	Applicant(s)	YUE ET AL.
Examiner	Delia M. Ramirez	Art Unit	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,9,10 and 29-45 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1,2,9,10 and 29-45 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.	6) <input type="checkbox"/> Other: ____.

DETAILED ACTION

Status of the Application

Claims 1-2, 9-10, 29-45 are pending.

Applicant's cancellation of claims 3-8, 11-28 in Paper No. 4, filed on 7/18/2001 is acknowledged.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, 9 drawn to a polypeptide having the amino acid sequence of SEQ ID NO: 1 and a method of producing said polypeptide, classified in class 530, subclass 350.
 - II. Claims 10, 30, 31, 33, 36-37, 39-42, 45, drawn to an antibody that specifically binds to the polypeptide of SEQ ID NO: 1, classified in class 530, subclass 387.1.
 - III. Claim 29, drawn to a diagnostics test of a condition associated with CJPDZ, classified in class 436, subclass 512.
 - IV. Claims 32, 34, drawn to a method of diagnosing a condition associated with CJPDZ in vivo, classified in class 424, subclass 9.1.
 - V. Claim 35, drawn to a method of preparing a polyclonal antibody, classified in class 436, subclass 547.
 - VI. Claim 38, drawn to a method of preparing a monoclonal antibody, classified in class 436, subclass 548.

VII. Claim 43, drawn to a method for detecting the polypeptide of SEQ ID NO: 1, classified in class 436, subclass 501.

VIII. Claim 44, drawn to a method for purifying the polypeptide of SEQ ID NO: 1, classified in class 436, subclass 532.

The inventions are distinct, each from the other because of the following reasons:

2. The polypeptide of Group I is related to the antibody of Group II by virtue of being the cognate antigen needed to create such antibody. However, they are patentably distinct inventions because the protein of Group I and the antibody of Group II are different physical and chemical entities, and because the protein can be used in other processes different from producing the antibody of Group II, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein, or to assay for antagonists/agonists.

3. Inventions II and III, IV, VII, or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention II can be used in the diagnosis test of Invention III or the methods of Inventions IV, VII, or VIII.

4. Inventions I and V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the protein of Invention I can be used in the methods of Inventions V or VI.

5. Inventions I and III, IV, VII, or VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Invention I is neither used nor made by the diagnosis test of Invention III nor the methods of Inventions IV, VII, or VIII.

6. Inventions II and V or VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of Invention II can be made by the different methods of Inventions V or VI.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
February 12, 2002

